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U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(37 CFR 1.98(b))

ATTY DOCKET NO.: 249.P2

SERIAL NO.: 10/785,497

APPLICANT: Becker et al.

Examiner: Paul C. Martin

FILING DATE: 2/24/04

GROUP ART UNIT: 1657

U.S. PATENT DOCUMENTS

| Examiner initials | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Class/ Subclass | Filing Date |
|-------------------|------------------|--------------------------------|--|--------------------|-------------------------|
| /PM/ | 5,053,215 | 10-01-1991 | Rand et al | | 05-26-1988 |
| | 5,413,996 | 05-09-1995 | Bodor, Nicholas | | 10-16-1992 |
| | 5,624,894 | 04-29-1997 | Bodor, Nicholas | | 04-27-1995 |
| | 5,627,165 | 05-06-1997 | Glazier, Arnold | | 09-23-1994 |
| | 5,663,159 | 09-02-1997 | Starrett, Jr. et al. | 514/181 | 10-11-1994 |
| | 5,792,756 | 08-11-1998 | Kucherov et al. | | 09-24-1996 |
| | 5,798,340 | 08-25-1998 | Bischofberger et al. | | 09-16-1994 |
| | 5,977,061 | 11-02-1999 | Holy et al. | | 04-21-1995 |
| | 5,977,089 | 11-12-1999 | Arimilli et al. | | 11-06-1998 |
| | 6,169,078 | 01-02-2001 | Hughes et al | | 05-12-1998 |
| | 6,245,750 | 06-12-2001 | Shepard, Michael | | 01-22-1999 |
| | 6,339,151 | 01-15-2002 | Shepard et al | | 01-22-1999 |
| | 6,348,185 | 02-19-2002 | Piwnica-Worms, David | | 06-18-1999 |
| | 6,355,629 | 03-12-2002 | Kozak | | 02-06-2001 |
| | 6,436,437 | 08-20-2002 | Yatvin et al | | 02-15-2000 |
| | US2001/0031873 | 10-18-2001 | Greenwald et al | | 01-12-2001 |
| /PM/ | US2002/0120100A1 | 08-29-2002 | Bonny | | 10-15-2001 ⁻ |

FOREIGN PATENT DOCUMENTS

| Examiner initials | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Class/ Subclass | Translation Yes/No |
|-------------------|-------------------------|--------------------------------|--|--------------------|-----------------------|
| /PM/ | EP 0 336 364 A2 | 10-11-1989 | NEORX CORPORATION | | |
| /PM/ | EP 0 481 214 A1 | 04-22-1992 | BRISTOL-MEYERS SQUIBB COMPANY | | |
| /PM/ | WO 00/18775 | 04-06-2000 | | : | |

EXAMINER

/Paul Martin/

DATE CONSIDERED

05/14/2007

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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|-------------------|-------------------------|--------------------------------|--|--------------------|-----------------------|
| /PM/ | WO 96/29336 | 09-26-1996 | Medical Research Council | | |
| /PM/ | WO 96/33200 | 10-24-1996 | Ustav Organicke Chemie A Biochemie Akademie Ved | | |
| /PM/ | WO 96/37503 | 11-28-1996 | GENTA INCORPORATED | | |

OTHER DOCUMENTS

| Examiner initials | Article | | | | |
|-------------------|--|--|--|--|--|
| /PM/ | Aarons et al., "Pharmacokinetic Evaluation of Site-Specific Drug Delivery Systems", 12:121-126, Novel Drug Delivery and Its Therapeutic Application (John Wiley & Sons), 1989 | | | | |
| | Banerjee et al., "Design of Prodrugs Based on Enzyme-Substrate Specificity", Chapter 2, pp. 118- 121, DESIGN OF PRODRUGS, 1985 | | | | |
| | Brunel et al., "A Practical Method for the Large-Scale Synthesis of Diastereomerically Pure (2R,5S)-3-Phenyl-2-(8-quinolinoxy)-1,3-diaza-2-phosphabicyclo-[3.3.0]-octane Ligand (QUIPHOS)", 64:8940-8942, J ORG CHEM, 1999 | | | | |
| | Bundgaard, H., "Design of Prodrugs: Bioreversible Derivatives for Various Functional Groups and Chemical Entities", Chapter 1, pp. 70-92, DESIGN OF PRODRUGS, 1985 | | | | |
| | Chapman et al., "Practical Synthesis, Separation, and Stereochemical Assignment of the PMPA Pro-Drug GS-7340", 20(4-7):621-628, Nucleosides, Nucleotides & Nucleic Acids, 2001 | | | | |
| | Connors, T.A., "Prodrugs in Cancer Chemotherapy", Chapter 9, pp. 291-316, DESIGN OF PRODRUGS, 1985 | | | | |
| | Jones, Geraint, "Decreased Toxicity and Adverse Reactions via Prodrugs", Chapter 6:pp. 199-241, DESIGN OF PRODRUGS, 1985 | | | | |
| | Kumar et al., "Heterocalixarenes. 1. Calix[2]uracil[2]arene: Synthesis, X-ray Structure, Conformational Analysis, and Binding Character", 64:7717-7726, J ORG CHEM, 1999 | | | | |
| | McGuigan et al., "Aryl phosphate derivatives of AZT retain activity against HIV1 in cell lines which are resistant to the action of AZT", 17:311-321, ANTIVIRAL RES, 1992 | | | | |
| | McGuigan et al., "Aryl Phosphate Derivatives of AZT Inhibit HIV Replication in Cells Where the Nucleoside is Poorly Active", 2(7):701-704, BIOORG MED CHEM LETT, 1992 | | | | |
| V | McGuigan et al., "Certain phosphoramidate derivatives of dideoxy uridine (ddU) are active against HIV and successfully by-pass thymidine kinase", 351:11-14, FEBS, 1994 | | | | |
| /PM/ | McGuigan et al., "Intracellular Delivery of Bioactive AZT Nucleotides by Aryl Phosphate Derivatives of AZT", 36:1048-1052, J MED CHEM, 1993 | | | | |

EXAMINER

/Paul Martin/

DATE CONSIDERED

05/14/2007

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

JUL 1 9 2004

PAGE 3 of 3

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| Examiner initials | Article McGuigan et al., "Phosphoramidates as potent prodrugs of anti-HIV nucleotides: studies in the amino region", 7(1):31-36, ANTIVIRAL CHEM & CHEMO, 1996 | | | | |
|-------------------|---|--|--|--|--|
| /PM/ | | | | | |
| 1 | Notari, Robert E., "Pharmacokinetic Aspects of Prodrug Design and Evaluation", Chapter 3, pp. 135-156, DESIGN OF PRODRUGS, 1985 | | | | |
| | Oliyai et al., "Aryl Ester Prodrugs of Cyclic HPMPC. I: Physicochemical Characterization and In Vitro Biological Stability", 16(11):1687-1693, PHARM RES, 1999 | | | | |
| - | Siddiqui et al., "Design and Synthesis of Lipophillic Phosphoramidate d4T-MP Prodrugs Expressing High Potency Against HIV in Cell Culture: Structural Determinants for in Vitro Activity and QSAR", 42:4122-4128, PHARM RES, 1999 | | | | |
| | Starrett et al., "Synthesis, Oral Bioavailability Determination, and in Vitro Evaluation of Prodrugs of the Antiviral Agent 9-[2-(Phosphonomethoxy)ethyl]adenine (PMEA)", 37:1857-1864, J MED CHEM, 1994 | | | | |
| | Stella et al., "Site-Specific Drug Delivery via Prodrugs", Chapter 5, pp. 177-198, DESIGN OF PRODRUGS, 1985 | | | | |
| V | Stella, Valentino J., "Prodrugs and Site-Specific Drug Delivery", 23(12):1275-1282, J MED CHEM, December 1980 | | | | |
| /PM/ | Strube et al., "Comparison of Batch Elution and Continuous Simulated Moving Bed Chromatography", 2:305-319, ORGANIC PROCESS RESEARCH & DEVELOPMENT, 1998 | | | | |

EXAMINER

/Paul Martin/

DATE CONSIDERED

05/14/2007

EXAMINER: Initial citation considered. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.